K133269

MAY 2 2 2014

ZOLL®

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510(k) Summary:

Applicant's Name and Address:	ZOLL Medical Corporation 269 Mill Road Chelmsford, MA 01824
Application Correspondent:	Tanmay Shukla 978-421-9171
Date Summary Prepared:	December 23, 2013
Classification:	Class III
Device Name	ZOLL X Series
Product Code	Automated External Defibrillators (MKJ) Cardiopulmonary Resuscitation Aid (LIX) Low-Energy – Defibrillators (LDD) Cardiac Monitors – including Cardiotachometer and Rate Alarms (DRT) External Transcutaneous Cardiac Non-Invasive Pacemaker (DRO) Noninvasive Blood Pressure Measurement System (DXN) Blood Pressure Computer (DSK) Carbon Dioxide Gas Analyzer (CCK) Oximeter (DQA)

Predicate Devices ZOLL X Series (K112432)
ZOLL R Series (K120907)

Description:

The ZOLL X Series Defibrillator/Monitor cleared under 510k application K112432 is a light weight, portable device designed to be used by trained medical personnel who are familiar with vital signs monitoring and emergency cardiac care. As in its previously cleared configuration, the modified X Series combines the functions of a Semi-automatic (AED)/ manual defibrillator, external transcutaneous pacer and patient monitor (including ECG, SpO2, SpCO, SpMet, CO2, NIBP, IBP, temperature and impedance respiration monitoring).

X Series software has been revised to support the OneStep Pediatric CPR Electrode. This electrode was previously cleared for use with the ZOLL R Series (K120907). As in the R Series, the electrode will enable the X Series device to provide CPR monitoring for Pediatric patients. The labeling of the X Series will be revised to remove the contraindication "The CPR monitoring function is not intended for use on patients under 8 years of age" from the Indications For Use for CPR Monitoring currently cleared for the X Series (K112432).

Indications for Use:

The X Series is intended for use by trained medical personnel who are familiar with basic monitoring, vital sign assessment, emergency cardiac care, and the use of the X Series. The X Series is also intended for use by (or on the order of) physicians at the scene of an emergency or in a hospital emergency room, intensive care unit, cardiac care unit, or other similar areas of a hospital. The usage may be in an ambulance or at the scene of an emergency. It is also intended to be used during the transport of patients. The X Series will be used primarily on patients experiencing symptoms of cardiac arrest or in post trauma situation. It may also be used whenever it is required to monitor any of those functions that are included (as options) in the device. The X Series unit can be used on pediatric patients (as described in the following table) and on adult patients (21 years of age or older) with and without heart dysfunction.

Pediatric Patient Subpopulation	Approximate Age Range
Newborn (neonate)	Birth to 1 month of age.
Infant	1 month to 2 years of age.
Child	2 to 12 years of age.
Adolescent	12 to 21 years of age.

When the pediatric patient is less than 8 years of age or weighs less than 55 lbs. (25 kg.), use ZOLL pediatric defibrillation electrodes. Do not delay therapy to determine the patient's exact age or weight.

Manual Defibrillation

Use of the X Series in the manual mode for external and internal defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness.
- Absence of breathing.
- Absence of pulse.

This product should be used only by qualified medical personnel for converting ventricular fibrillation and rapid ventricular tachycardia to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heart beats.

The unit can also be used for synchronized cardioversion of certain atrial or ventricular arrhythmias. Qualified medical personnel must decide when synchronized cardioversion is appropriate.

The patient population will range from newborn (neonate) to adult.

Semiautomatic Operation (AED)

X Series products are designed for use by emergency care personnel who have completed training and certification requirements applicable to the use of a defibrillator where the device operator controls delivery of shocks to the patient.

They are specifically designed for use in early defibrillation programs where the delivery of a defibrillator shock during resuscitation involving CPR, transportation, and definitive care are incorporated into a medically-approved patient care protocol.

Use of the X Series in the Semiautomatic mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness.
- Absence of breathing.
- Absence of pulse.

When the patient is less than 8 years of age or weighs less that 55 lbs. (25 Kg), you must use ZOLL pediatric defibrillation electrodes. Do not delay therapy to determine patient's exact age or weight.

ECG Monitoring

The X Series is intended for use to monitor and/or record 3-, 5-, or 12-lead ECG waveform and heart rate, and to alarm when heart rate is above or below limits set by the operator. The patient population will range from newborn (neonate) to adult, with and without heart dysfunction.

CPR Monitoring

The CPR monitoring function provides visual and audio feedback designed to encourage rescuers to perform chest compressions at the AHA/ERC recommended rate of 100 compressions per minute. Voice and visual prompts encourage a minimum compression depth of at least 1.5 (3.8 cm) or 2.0 inches (5.0 cm), depending on the configuration, for adult patients.

External Transcutaneous Pacing

This product can be used for temporary external cardiac pacing in conscious or unconscious patients as an alternative to endocardial stimulation. The purposes of pacing include:

- Resuscitation from standstill or bradycardia of any etiology:
- As a standby when standstill or bradycardia might be expected:
- Suppression of tachycardia.
- Pediatric pacing.

Non-Invasive Blood Pressure Monitoring

The X Series is intended for use to make non-invasive measurements of arterial pressure and heart rate, and to alarm if either parameter is outside of the limits set by the user. Measurements are made using an inflatable cuff on the patient's arm or leg. The patient population will range from newborn (neonate) to adult.

Temperature Monitoring

The X Series is intended for use to make continuous temperature measurements of rectal, esophageal, or surface temperatures, and to alarm if the temperature is outside of the limits set by the user. The patient population will range from newborn (neonate) to adult.

SpO2 Monitoring

The X Series pulse CO-oximeter, with Masimo Rainbow SET technology and the Rainbow series of sensors, is intended for use for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), and/or methemoglobin saturation (SpMet). The pulse CO-oximeter and accessories are indicated for use on adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, or in mobile environments.

Respiration Monitoring

The X Series is intended for use to continuously monitor respiration rate and to alarm if the rate falls outside of the range set by the operator. Because the measurement method actually measures respiratory effort, apnea episodes with continued respiratory effort (such as obstructive apnea) may not be detected. It is not intended to be used as an apnea monitor. The patient population will range from newborn (neonate) to adult.

CO2 Monitoring

The X Series is intended for use to make continuous noninvasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and breath rate. The patient population will range from newborn (neonate) to adult.

Invasive Pressure Monitoring

The X Series is intended for use to display and make continuous invasive pressure measurements from any compatible pressure transducer. The primary intended uses are arterial blood pressure, central venous pressure and intracranial pressure monitoring. Any contraindications of the particular transducer selected by the user shall apply. The patient population will range from newborn (neonate) to adult.

12-Lead Analysis

The 12-lead ECG Analysis is intended for use in acquiring, analyzing and reporting ECG data, and to provide interpretation of the data for consideration by caregivers. The interpretations of ECG data offered by the device are only significant when used in conjunction with caregiver overread as well as

consideration of all other relevant patient data. The 12-lead ECG Analysis is intended for use on adults (> 18 years of age).

Substantial Equivalence – Non-Clinical Evidence:

Features and functions cleared with the predicate device ZOLL X Series (K112432) have remained unchanged in the proposed version of the device. Support for the CPR monitoring feature of the OneStep Pediatric CPR Electrode is added through a software revision. As in the R Series (K120907), the electrode will enable the X Series device to provide CPR monitoring for Pediatric patients. Safety, efficacy and substantial equivalence was shown through software verification and system level validation.

Substantial Equivalence – Clinical Evidence:

N/A - Clinical evidence was not necessary to show substantial equivalence

Comparison of Technological Characteristics

Features and functions cleared with the predicate ZOLL X Series (K112432) have remained unchanged in the proposed version of the device. Support for the CPR monitoring feature of the OneStep Pediatric CPR Electrode is added through a software revision. As in the R Series (K120907), the electrode will enable the X Series device to provide pediatric CPR monitoring information specifically, the CPR timer and the numeric display of the actual rate and depth of chest compression.

Performance Testing:

Extensive performance testing in the form of the software verification and system level validation ensures that the ZOLL X Series performs as well as the indicated predicate devices and meets all of its functional requirements and performance specifications. Safety testing assures that the device complies with applicable sections of recognized industry and safety standards.

Conclusion

The information provided in this 510(k) demonstrates that the ZOLL X Series' features and functions are substantially equivalent to those of the indicated commercially distributed devices with regard to performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
WO66-G609
Silver Spring, MD 20993-0002

May 22, 2014

Zoll Medical Corporation, World Wide Headquarters
Tanmay Shukla
269 Mill Road
Chelmsford, MA 01824-4105 US

Re: K133269
Trade/Device Name: Zoll X Series
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillators (Non-Wearable)
Regulatory Class: Class III
Product Code: MKJ
Dated: April 22, 2014
Received: April 23, 2014

Dear Mr. Tanmay Shukla,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

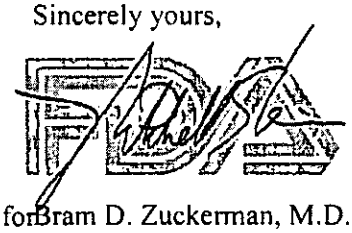
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): K133269

Device Name: X Series AED

Intended Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA Date: 2014.05.22 09:30:50 -04'00'

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